510(k) SUMMARY FOR K121216

NOV 2 1 2012

Soft Tissue Regeneration, Inc. - The STR GRAFT

In accordance with 21 CFR 878.3300, the following information is a summary of the 510(k) information regarding Soft Tissue Regeneration Inc.'s STR GRAFT device.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, LLC.
Submitter Address:	815 Iris Lane, Vero Beach, FL 32963
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796; (973) 738-6097
Fax Number:	(514) 901-0796
Date of Submission:	November 20, 2012

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Soft Tissue Regeneration, Inc.
Manufacturer Address:	142 Temple Street, Suite 206, New Haven, CT 06510, USA
Registration Number:	To be determined
Contact Name:	Joseph Reilly
Title:	President
Device Trade Name:	STR GRAFT
Device Common Name:	Surgical mesh
Classification Name:	Surgical Mesh; Polymeric
Classification Codes:	OWT and OWW – Both are Class II
Classification Panel:	General and Plastic Surgery
Regulation Number:	21 CFR § 878.3300

C. PREDICATE DEVICES

K083307	X-Repair; manufactured by Synthasome, Inc.
K071887	Sport Mesh, Artelon Tissue Reinforcement; manufactured by Artimplant AB
K052830	Sport Mesh; manufactured by Artimplant AB

D. DEVICE DESCRIPTION

The STR GRAFT is a bioresorbable, three-dimensionally (3-D) braided construct made of poly-L-lactic-acid (PLLA) fiber. The STR GRAFT is available in rectangular and square sizes of 23 mm x 12 mm, 23 mm x 23 mm, 23 mm x 40 mm, and 23 mm x 60 mm; all STR GRAFT devices are approximately 1.0 mm thick; with the thickness comprised of three layers of 3-D braided fiber bundles. The STR GRAFT is supplied sterile (EtO) and is single-use only.

E. INTENDED USE

The STR GRAFT is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

The STR GRAFT is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

The STR GRAFT is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures used to repair the tear, and sutures or bone anchors, used to attach the tissue to bone, provide mechanical strength for the tendon repair.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of Soft Tissue Regeneration's STR GRAFT devices are the same or similar to the cited predicated devices. The subject STR GRAFT device is fabricated from PLLA fiber; the predicate device X-Repair is also fabricated with PLLA fiber. The sizes and thickness of the STR GRAFT and X-Repair are similar. The principle difference with X-Repair is that the STR GRAFT is fabricated via a proprietary 3-D braiding technology; X-Repair is a simple two-dimensional woven construct. The STR GRAFT possesses similar sizes and thickness as Artimplant's SportMesh device; SportMesh is also fabricated from a bioresorbable fiber material (Artelon). The STR GRAFT is surgically attached to soft tissue and/or anchored to underlying bony structures with sutures, which is the same means of implantation as the cited predicate devices. The indications for use for the subject STR GRAFT is identical to that for the predicate X-Repair device and similar in intended use as Artimplant's SportMesh. Biocompatibility, physical, and mechanical testing per the FDA Guidance Document for Soft Tissue Mesh implants and ISO standards for biocompatibility show the minor technological differences between the subject STR GRAFT and predicate X-Repair and SportMesh devices do not raise new types of safety and efficacy issues; the STR GRAFT is therefore substantially equivalent to the cited predicate devices.

G. PERFORMANCE DATA

Characterization of STR GRAFT devices was performed per the FDA Guidance Document entitled "FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" issued on March 2, 1999 and ISO 10993 standards for biocompatibility. More specifically, mechanical testing of the devices was performed per ASTM Standards F-2150-07, D3787-07, D2261-07a, D882-10, F2392-04, F1877-05, D4032-08, and D6767-11; the test methods were modified as appropriate regarding the length and width of the STR GRAFT. Biocompatibility testing was performed per ISO Standards 10993-3, -5, -7, -10, and -11. In addition, a 12 week ovine model of rotator cuff repair was performed. The results of physical, mechanical, in-vivo, and biocompatibility testing indicate that the STR GRAFT possesses appropriate physical and mechanical characteristics for reinforcement of soft tissues where weakness exists.

G. CONCLUSION

The materials used in manufacture, the results of physical and mechanical testing per the FDA Guidance document for surgical mesh and ASTM standards, the results of biocompatibility testing per ISO 10993 standards, design features, in vivo animal testing and a comparable intended use support a determination that the STR GRAFT is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Soft Tissue Regeneration, Incorporated
% Biovera, LLC
Mr. Robert A. Poggie, Ph.D.
President
815 Iris Lane
Vero Beach, Florida 32963

Letter Dated: November 21, 2012

Re: K121216
Trade/Device Name: STR GRAFT
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OWT, OWW
Dated: October 26, 2012
Received: November 07, 2012

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K121216**

Device Name: STR GRAFT

Indications For Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR...	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

David Krause
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(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121216